



UNITED STATES PATENT AND TRADEMARK OFFICE

cll

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,506	03/29/2004	Daniel D. Shoemaker	9301-235-999	5273
20583	7590	09/14/2006		
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017				
EXAMINER STAPLES, MARK				
ART UNIT			PAPER NUMBER	
1637				

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/813,506	Applicant(s) SHOEMAKER ET AL.	
	Examiner Mark Staples	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 122,178 and 185-232 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 122,178 and 185-232 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 122 and claims 185-232, drawn to arrays of polynucleotides, classified in class 435, subclass 40.5.
- II. Claim 178, drawn to a method for preparing an array of polynucleotides, classified in class 536, subclass 25.3.

2. The inventions are independent or distinct, each from the other because:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process, the probes of Invention I can be made by enzymatic cleavage of a naturally occurring nucleic acid. Invention II requires the probes be made by synthesizing a plurality of probes. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Searching the inventions of Groups I and II together would impose a serious search burden. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the positionally-addressable ordered arrays of polynucleotide probes of Group I and the method of Group II for preparing an array comprising synthesizing a plurality of probes are not coextensive. Group II requires searching the synthesis of a plurality of probes, which is not required for the search of Group I. In contrast, the search for Group II would require a text search for the method of synthesizing polynucleotides in addition to the array. Prior art which teaches preparing probes by enzyme digestion would not necessarily be applicable to the method of synthesizing probes of Group II. Moreover, even if the arrays of Group I were known, the method of preparing the arrays may be novel and unobvious in view of the preamble or active steps. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Election of Species

3. This application contains claims directed to the following patentably distinct species in the arrays of Group I as follows.

Group I

1. Array range

- a. 150 to 1,000 different polynucleotides per cm^2 (claim 186 in part)
- b. 1,000 to 10,000 different polynucleotides per cm^2 (claim 187 in part)
- c. 10,000 to 50,000 different polynucleotides per cm^2 (claim 188 in part)
- d. greater than 50,000 polynucleotides per cm^2 (claim 189 in part)

2. Probe Proximity

- a. genomic sequences for different probes are overlapping (claim 190 in part)
- b. genomic sequences for different probes are adjacent (claims 191 in part)
- c. genomic sequences for each probe is set apart from other probes by less than 200 bp (claims 192 in part)

3. Probe Size and Proximity

- a. nucleotide sequences of probes are no more than 1,000 nucleotides (claim 193 in part)
 - i. genomic sequences for different probes are overlapping (claim 194 in part)
 - ii. genomic sequences for different probes are adjacent (claim 195 in part)

- iii. genomic sequences for each probe is set apart from other probes by less than 200 bp (claim 196 in part)
- b. nucleotide sequences of probes are 10-200 nucleotides (claim 197 in part)
 - i. genomic sequences for different probes are overlapping (claim 198 in part)
 - ii. genomic sequences for different probes are adjacent (claim 199 in part)
 - iii. genomic sequences for each probe is set apart from other probes by less than 200 bp (claim 200 in part)
- c. nucleotide sequences of probes are 10-30 nucleotides (claim 201 in part)
 - i. genomic sequences for different probes are overlapping (claim 202 in part)
 - ii. genomic sequences for different probes are adjacent (claim 203 in part)
 - iii. genomic sequences for each probe is set apart from other probes by less than 200 bp (claim 204 in part)
- d. nucleotide sequences of probes are 20-50 nucleotides (claim 205 in part)

- i. genomic sequences for different probes are overlapping (claim 206 in part)
 - ii. genomic sequences for different probes are adjacent (claim 207 in part)
 - iii. genomic sequences for each probe is set apart from other probes by less than 200 bp (claim 208 in part)
- e. nucleotide sequences of probes are 40-80 nucleotides (claim 209 in part)
 - i. genomic sequences for different probes are overlapping (claim 210 in part)
 - ii. genomic sequences for different probes are adjacent (claim 211 in part)
 - iii. genomic sequences for each probe is set apart from other probes by less than 200 bp (claim 212 in part)
- f. nucleotide sequences of probes are 50-150 nucleotides (claim 213 in part)
 - i. genomic sequences for different probes are overlapping (claim 214 in part)
 - ii. genomic sequences for different probes are adjacent (claim 215 in part)

Art Unit: 1637

- iii. genomic sequences for each probe is set apart from other probes by less than 200 bp (claim 216 in part)
- g. nucleotide sequences of probes consist of 60 nucleotides (claim 217 in part)
 - i. genomic sequences for different probes are overlapping (claim 218 in part)
 - ii. genomic sequences for different probes are adjacent (claim 219 in part)
 - iii. genomic sequences for each probe is set apart from other probes by less than 200 bp (claim 220 in part)
- 4. First Plurality of Probes
 - a. is at least 1,000 probes (claim 225 in part)
 - b. is at least 10,000 probes (claim 226 in part)
 - c. is in the range 1,000 to 50,000 probes (claim 227 in part)

The species are independent or distinct because each species is a patentably distinct molecule or combination of molecules.

This application contains claims directed to the following patentably distinct species for Group I: array ranges, probe proximity, probe size and proximity, and first plurality of probes.

The species are independent or distinct because each, each array range is a different and patentably distinct combination, each probe by proximity and or size is a structurally different and patentably distinct molecule, and each first plurality of probes is a different and patentably distinct combination.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 122, 178, 221-224, and 228-232 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

For Group I, that means applicant must elect a single species of array ranges, a single species of probe proximity or a single species of probe size and proximity, and a single species of first plurality of probes.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Because these species are independent or distinct for the reasons given above and the species require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Notice of Possible Rejoinder

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is

Art Unit: 1637

subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116;

amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Close

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1637

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples *MS*
Examiner
Art Unit 1637
September 6, 2006

Kenneth R. Horlick
KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
9/6/06